K040483

JUL 2 3 2004

EQUESTRA™ Fluid Delivery System
510(k) Summary
June 2004

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Richard W. Treharne, PhD**
Senior Vice President Regulatory Affairs

II. **Proprietary Trade Name: EQUESTRA™ Fluid Delivery System**

III. **Classification Name: Orthopedic Manual Surgical Instrument**

IV. **Regulation Number: 888.4540, 878.4800 and 878.4200**

V. **Product Description**

The EQUESTRA™ Fluid Delivery System is designed to provide surgeons with a means to inject commercially cleared bone cement to the surgical site in orthopedic procedures. The EQUESTRA™ Fluid Delivery System does not contain any bone cement material, as this system only consists of general instruments.

The EQUESTRA™ Fluid Delivery System consists of a variety of general surgical instruments. The system reservoirs are supplied empty as the system itself does not include any bone cement. Included in the system are bone tamps and stylets. All of the system components are manual, single-use disposable instruments.

VII **Indications**

The EQUESTRA™ Delivery System is intended to provide surgeons with a percutaneous means of delivering legally cleared bone cement to the surgical site in orthopedic procedures.

VIII **Substantial Equivalence**

Documentation was provided which demonstrated the EQUESTRA™ Delivery System to be substantially equivalent to various Class I exempt instruments including bone tamps, cannulas and stylets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K040483
Trade/Device Name: EQUESTRA™ Fluid Delivery System
Regulation Number: 21 CFR 888.1100, 21 CFR 888.4540
Regulation Name: Arthroscope; Orthopedic manual surgical instrument
Regulatory Class: II
Product Code: HRX, HXG
Dated: June 22, 2004
Received: June 23, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

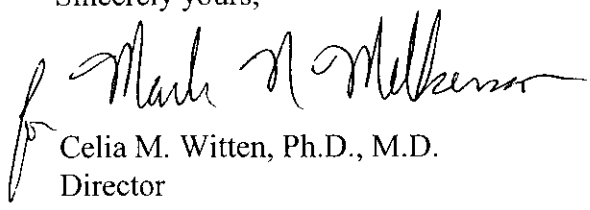
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040483

Device Name: EQUESTRA™ Fluid Delivery System

Indications for Use:

The EQUESTRA™ Delivery System is intended to provide surgeons with a percutaneous means of delivering legally cleared bone cement to the surgical site in orthopedic procedures.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040483